

PATENT #2

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In re Application of:

Fallaux et al.

Serial No.: To be assigned

Filed: October 23, 2001

For: PACKAGING SYSTEMS FOR HUMAN
RECOMBINANT ADENOVIRUS TO BE
USED IN GENE THERAPY

Examiner: To be assigned

Group Art Unit: To be assigned

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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record.

In accordance with 37 C.F.R. § 1.97(g) and (h), filing of this Information Disclosure Statement is not to be construed as a representation that a search has been made or an admission that the information cited herein is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b). Further, no representation is made by Applicants herein that no other possible material information as defined in 37 C.F.R. § 1.56 (b) exists.

Pursuant to 37 C.F.R. § 1.98(d), a copy of any patent, publication or other information listed in the Information Disclosure Statement is not required to be provided if it was previously cited by or submitted to the office in a prior application, provided that the prior application is properly identified in the statement and relied upon for an earlier filing date under 35 U.S.C. § 120.

Accordingly, no copy of information marked with a pound sign (#) is enclosed because it was previously cited or submitted to the patent office in a prior application which is properly identified above, and is relied upon for an earlier filing date. The references are as follows:

DOCUMENTS

U.S. Patent Documents

<u>U.S. Patent No.</u>	<u>Issue Date</u>	<u>Inventor</u>
#4,405,712	09/20/83	Vande Woude et al.
#4,497,796	02/05/85	Salser et al.
#4,727,028	02/23/88	Santerre et al.
#4,740,463	04/26/88	Weinberg et al.
#5,190,931	03/02/93	Inouye
#5,208,149	05/04/93	Inouye
#5,378,618	01/03/95	Sternberg et al.
#5,518,913	05/21/96	Massie et al.
#5,545,522	08/13/96	Van Gelder et al.
#5,652,224	07/29/97	Wilson et al.
#5,670,488	09/23/97	Gregory et al.
#5,707,618	01/13/98	Armentano et al.
#5,753,500	05/19/98	Shenk et al.
#5,994,106	11/30/99	Kovesdi et al.
#5,837,511	11/17/98	Falck-Pedersen et al.
#5,994,128	11/30/99	Fallaux et al.
#6,033,908	03/07/2000	Bout et al.

#6,040,174

03/21/2000

Imler et al.

Foreign Patent Documents

<u>Document No.</u>	<u>Date</u>	<u>Country</u>
#2,053,187	04/11/93	Canada
#WO 94/08026	04/14/94	PCT
#WO 94/11506	05/26/94	PCT
#WO 94/12649	06/09/94	PCT
#WO 94/23582	10/27/94	PCT
#WO 94/24297	10/27/94	PCT
#WO 94/26914	11/24/94	PCT
#WO 94/28152	12/08/94	PCT
#WO 94/28938	12/22/94	PCT
#WO 95/00655	01/05/95	PCT
#2 707 664	01/20/95	France
#WO 95/02697	01/26/95	PCT
#95201611.1	06/15/95	EP
#WO 95/16772	06/22/95	PCT
#95201728.3	06/26/95	EP
#2,117,668	09/10/95	Canada
#WO 95/26411	10/05/95	PCT
#WO 95/27071	10/12/95	PCT
#WO 95/34671	12/21/95	PCT
#AU-A-28533/95	03/21/96	Australia
#WO 96/13596	05/09/96	PCT
#WO 96/14061	05/17/96	PCT
#WO 96/16676	06/06/96	PCT
#WO 96/18418	06/20/96	PCT
#WO 96/33280	10/24/96	PCT

#WO 96/40955	12/19/96	PCT
#WO 97/00947	01/09/97	PCT
#WO 97/04119	02/06/97	PCT
#WO 97/05255	02/13/97	PCT

Other Documents

#Amalfitano et al., "Improved adenovirus packaging cell lines to support the growth of replication-defective gene-delivery vectors", Proc. Natl. Acad. Sci. USA, 93:3352-3356, April 1996.

#Amalfitano et al., "Isolation and characterization of packaging cell lines that coexpress the adenovirus E1, DNA polymerase, and preterminal proteins: implications for gene therapy", Gene Therapy, 4:258-263, 1997.

#Armentano et al., "Characterization of an Adenovirus Gene Transfer Vector Containing an E4 Deletion", Human Gene Therapy, 6:1343-1353, October 1995.

#Bernards, Rene, et al., "Characterization of Cells Transformed by Ad5/Ad12 Hybrid Early Region I Plasmids", Virology, 120:422-432, 1982.

#Bernards, Rene, et al., "Role of Adenovirus Types 5 and 12 Early Region 1b Tumor Antigens in Oncogenic Transformation", Virology, 127:45-53, 1983.

#Brough et al., "A Gene Transfer Vector-Cell Line System for Complete Functional Complementation of Adenovirus Early Regions E1 and E4", Journal of Virology, 70(9):6497-6501, September 1996.

#Brough et al., "Construction, Characterization, and Utilization of Cell Lines Which Inducibly Express the Adenovirus DNA-Binding Protein", Virology, 190:624-634, 1992.

#Brough et al., "Multiple Functions of the Adenovirus DNA-Binding Protein Are Required for Efficient Viral DNA Synthesis", Virology, 196:269-281, 1993.

#Brough et al., "Restricted changes in the adenovirus DNA-binding protein that lead to extended host range or temperature sensitive phenotypes", Journal of Virology, Vol. 55, pp. 206-212.

#Brough et al., "Stable Cell Lines for Complementation of Adenovirus Early Regions E1, E2A and E4; Abstract Book CSH Conference On Gene Therapy, 42, 1996.

#Caravokyri et al., "Constitutive Episomal Expression of Polypeptide IX (pIX) in a 293-Based Cell Line Complements the Deficiency of pIX Mutant Adenovirus Type 5", Journal of Virology, 69(11):6627-6633, November 1995.

#Engelhardt et al., "Ablation of E2A in recombinant adenoviruses improves transgene persistence and decreases inflammatory response in mouse liver", Proceeding of the National Sciences of USA, Vol. 91, pp. 6196-6200, 1994.

#Fallaux et al., "Characterization of 911: A New Helper Cell Line for the Titration and Propagation of Early Region 1-Deleted Adenoviral Vectors", Human Gene Therapy, 7:215-222, 1996.

#Fields et al., "Fields Virology", Second Edition, pp. 28-30, 87.

#Fisher et al., "Recombinant Adenovirus Deleted of All Viral Genes for Gene Therapy of Cystic Fibrosis", Virology, 217:11-22, 1996.

#Gao et al., "Biology of Adenovirus Vectors with E1 and E4 Deletions for Liver-Directed Gene Therapy", Journal of Virology, 70(12):8934-8943, December 1996.

#Gorziglia et al., "Elimination of both E1 and E2a from Adenovirus Vectors Further Improves Prospects for In Vivo Human Gene Therapy", Journal of Virology, 70(6):4173-4178, June 1996.

#Graham, F.L., et al., "Characteristics of a Human Cell Line Transformed by DNA from Human Adenovirus Type 5", J. gen. Virol., 36:59-74, 1977.

#Grodzicker, Terri, et al., "Expression of Unselected Adenovirus Genes in Human Cells Co-transformed with the HSV-1 tk Gene and Adenovirus 2 DNA", Cell, 21:453-463, September 1980.

#Hardy et al., "Construction of Adenovirus Vectors through Cre-lox Recombination", Journal of Virology, 71(3):1842-1849, March 1997.

#Hehir et al., "Molecular Characterization of Replication-Competent Variants of Adenovirus Vectors and Genome Modifications To Prevent Their Occurrence", Journal of Virology, 70(12):8459-8467, December 1996.

#Imler et al., "Novel complementation cell lines derived from human lung carcinoma A549 cells support the growth of E1-deleted adenovirus vectors", Gene Therapy, 3:75-84, 1996.

#Kornberg, Arthur, "DNA Replication", W.H. Freeman and Company, San Francisco, 4 pages (double sided).

#Krougliak et al., "Development of Cell Lines Capable of Complementing E1, E4, and Protein IX Defective Adenovirus Type 5 Mutants", Human Gene Therapy, 6:1575-1586, December 1995.

#Lemarchand et al., "Adenovirus-mediated transfer of a recombinant human α 1-antitrypsin cDNA to human endothelial cells", Proc. Natl. Acad. Sci. USA, Vol. 89, pp. 6482-6486, July 1992.

#Lieber et al., "Recombinant Adenoviruses with Large Deletions Generated by Cre-Mediated Excision Exhibit Different Biological Properties Compared with First-Generation Vectors In Vitro and In Vivo", Journal of Virology, 70:8944-8960, December 1996.

#Lochmuller, H., et al., "Emergence of Early Region 1-Containing Replication-Competent Adenovirus in Stocks of Replication-Defective Adenovirus Recombinants (Δ E1+ Δ E3) During Multiple Passages in 293 Cells", Human Gene Therapy, 5:1485-1491, December 1994.

#Louis, Nathalie, et al., "Cloning and Sequencing of the Cellular-Viral Junctions from the Human Adenovirus Type 5 Transformed 293 Cell Line", Virology, 233:423-429, 1997.

#Ngo et al., "in The Protein Folding Problem and Tertiary Structure Prediction", Merz et al., (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495, 1994.

#Orkin et al., "Reports and Recommendations of the Panel to Assess the NIH Investment in Research on Gene Therapy", 21 pages, December 7, 1995.

#Roberts, Bryan E., et al., "Individual Adenovirus Type 5 Early Region 1A Gene Products Elicit Distinct Alterations of Cellular Morphology and Gene Expression", Journal of Virology, pp. 404-413, Nov. 1985.

#Rosenfeld et al., "In Vivo Transfer of the Human Cystic Fibrosis Transmembrane Conductance Regulator Gene to the Airway Epithelium", Cell, Vol. 68, pp. 143-155, January 10, 1992.

#Sabatie et al., "Process Development for the Production of Second Generation Adenovirus Vectors for Gene Transfer in Clinical Protocols", Abstract Book 14th Meeting on Animal Cell Technology, BI-3, 1996.

#Schaack et al., "Adenovirus Type 5 Precursor Terminal Protein-Expressing 293 and HeLa Cell Lines", Journal of Virology, 69(7):4079-4085, July 1995.

#Stratford-Perricaudet, Leslie, et al., "Gene Transfer Into Animals: The Promise of Adenovirus, Human Gene Transfer", 219:51-61, 1991.

#Trapnell et al., "Gene therapy using adenoviral vectors", Current Opinion in Biotechnology, 5:617-625, 1994.

#Vaessen, R.T.M.J., "Adenovirus E1A-Mediated Regulation of Class I MHC Expression", The EMBO Journal, 5(2):335-341, 1986.

#Vaessen, R.T.M.J., "Different Adenovirus E1A-Controlled Properties of Transformed Cells Require Different Levels of E1A Expression", Gene, pp. 247-254, 1987.

#Vanhaesebroeck, Bart, et al., "Modulation of Cellular Susceptibility to the Cytotoxic/Cytostatic Action of Tumor Necrosis Factor by Adenovirus E1 Gene Expression Is Cell Type-Dependent", Virology, 176:362-368, 1990.

#Vos et al., "Characterization of Adenovirus Type 5 Insertion and Deletion Mutants Encoding Altered DNA Binding Proteins", Virology, 172, pp. 634-642, 1989.

#Wang et al., "A packaging cell line for propagation of recombinant adenovirus vectors containing two lethal gene-region deletions", Gene Therapy, 2:775-783, 1995.

#Weinberg et al., "A cell line that supports the growth of a defective early region 4 deletion mutant of human adenovirus type 2", Proc. Natl. Sci. USA, Vol. 80, pp. 5383-5386, September 1983.

#Yang et al., "Cellular immunity to viral antigens limits E1-deleted adenoviruses for gene therapy", Proc. Natl. Acad. Sci. USA, Vol. 91, pp. 4407-4411, May 1994.

#Yeh et al., "Efficient Dual Transcomplementation of Adenovirus E1 and E4 Regions from a 293-Derived Cell Line Expressing a Minimal E4 Functional Unit", Journal of Virology, 70(1):559-565, January 1996.

#Zhou et al., "Development of a Complementing Cell Line and a System for Construction of Adenovirus Vectors with E1 and E2a Deleted", Journal of Virology, 70(1):7030-7038, October 1996.

#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior applications:

Serial No.: 09/333,820

Filed: June 15, 1999

For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56 & 1.175, applicant hereby identifies the following listed copending applications naming the same inventors:

Serial No.: 08/820,479

Filed: 3/18/1997

For: METHODS AND COMPOSITIONS FOR GENETICALLY MODIFYING PRIMATE BONE MARROW CELLS

Serial No.: 08/973,560

Filed: 12/5/1997

For: P-53 BINDING PROTEIN CALLED MDMX AND ENCODING SEQUENCES FOR SAID PROTEIN

Serial No.: 09/214,836

Filed: 10/4/1999

For: MELANOMA ASSOCIATED PEPTIDE ANALOGUES AND VACCINES AGAINST MELANOMA

Serial No.: 09/298,745

Filed: 4/23/1999

For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY

Serial No.: 09/326,032

Filed: 6/4/1999

For: GENETIC MODIFICATION OF PRIMATE HEMOPOIETIC REPOPULATING STEM CELLS

Serial No.: 09/332,803

Filed: 6/14/1999

For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY

Serial No.: 09/333,820

Filed: 6/15/1999

For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY

Serial No.: 09/348,354
Filed: 7/7/1999
For: CHIMAERIC ADENOVIRUSES

Serial No.: 09/356,575
Filed: 7/19/1999
For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO
BE USED IN GENE THERAPY

Serial No.: 09/381,716
Filed: 1/4/2000
For: METHODS AND COMPOSITIONS FOR GENETICALLY MODIFYING
PRIMATE BONE MARROW CELLS

Serial No.: 09/444,284
Filed: 11/19/1999
For: GENE DELIVERY VECTORS PROVIDED WITH A TISSUE TROPISM FOR
SMOOTH MUSCLE CELLS, AND/OR ENDOTHELIAL CELLS

Serial No.: 09/502,624
Filed: 2/11/2000
For: VECTORS AND METHODS FOR PROVIDING CELLS WITH ADDITIONAL
NUCLEIC ACID MATERIAL INTEGRATED IN THE GENOME OF SAID CELLS

Serial No.: 09/506,548
Filed: 2/16/2000
For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO
BE USED IN GENE THERAPY

Serial No.: 09/517,898
Filed: 3/3/2000
For: MEANS AND METHODS FOR FIBROBLAST-LIKE OR MACROPHAGE-LIKE
CELL TRANSDUCTION

Serial No.: 09/549,463
Filed: 4/14/2000
For: RECOMBINANT PROTEIN PRODUCTION IN A HUMAN CELL

Serial No.: 09/573,740
Filed: 5/18/2000
For: SEROTYPES OF ADENOVIRUS AND USES THEREOF

Serial No.: 09/599,488

Filed: 6/23/2000

For: ADENO-ASSOCIATED VIRUS AND ADENOVIRUS CHIMERIC
RECOMBINANT VIRUSES USEFUL FOR THE INTEGRATION OF FOREIGN
GENETIC INFORMATION INTO CHROMOSOMAL DNA OF TARGET CELLS

Serial No.: 09/665,472

Filed: 9/20/2000

For: GENE DELIVERY VECTORS PROVIDED WITH A TISSUE TROPISM FOR
DENDRITIC CELLS

Applicants offer to supply any explanation or discussion of the documents which the Examiner feels is necessary or desirable and which is requested.

This Information Disclosure Statement is filed within three (3) months of the filing date of the above-identified application, and no certification pursuant to 37 C.F.R. § 1.97(c) or a fee pursuant to 37 C.F.R. 1.17(p) is required.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Allen C. Turner', with a long horizontal flourish extending to the right.

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Enclosure: Form PTO-1449

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